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Is It Time to Stop (or Pause) Vertebral Augmentation?

The approximately 750,000 osteoporotic vertebral fractures that occur every year in the United States result in considerable pain, disability, and impaired quality of life. The acute pain associated with a vertebral fracture generally diminishes over time but often takes months, leaving physicians caring for these patients struggling to find approaches to alleviate their discomfort. Aside from pain medications and non-pharmacological options such as bracing and exercise, vertebral augmentation therapy emerged in the 1990s as a surgical approach to reduce pain and deformity after a vertebral fracture. It was believed that bone cement injected into the fractured vertebra during this type of procedure fused the fragments of the vertebra together, thereby reducing motion of the fragments with movement and respiration, thus reducing bone pain. As currently practiced, vertebral augmentation includes either percutaneous vertebroplasty, where bone cement (polymethylmethacrylate [PMMA]) is injected percutaneously into the vertebral body, or balloon kyphoplasty, where a balloon or bone tamp is introduced into the vertebral body, inflated, and then injected with PMMA. The latter procedure has the added potential benefit of restoring vertebral height and reducing spinal deformity.

Despite the absence of clear evidence for efficacy and potential safety concerns, an estimated 81,690 patients underwent vertebroplasty and 169,413 patients underwent kyphoplasty in the United States between 2006 and 2014. Given this widespread usage of vertebral augmentation, the American Society for Bone and Mineral Research (ASBMR) leadership charged a Task Force to address key questions related to the efficacy and safety of vertebral augmentation and other non-pharmacological approaches (bracing, exercise) for the treatment of vertebral fracture. An initial Task Force report published in 2017 described pain, quality-of-life, and safety outcomes associated with kyphoplasty for vertebral fractures. The findings and recommendations of this second Task Force are presented in this issue.

The Task Force is to be commended for the comprehensive and thoughtful nature of their review of the evidence, which included a systematic review of the existing literature and meta-analyses. Their conclusions are clear. Vertebroplasty provides no clinically significant benefit in terms of pain control over placebo or sham procedures based on five randomized placebo-controlled trials. Kyphoplasty provided weak evidence of benefit in one clinical trial showing reduced pain compared with nonsurgical treatment, but lack of placebo-controlled trials, along with absence of any benefits of kyphoplasty over vertebroplasty when the two have been directly compared in a small number of heterogeneous head-to-head trials, argues against the routine use of this procedure also. Bracing and exercise, which are relatively safe and inexpensive, may provide some limited benefit.

The lack of clear benefits of vertebroplasty or kyphoplasty is compounded by concerns that these procedures, by altering the biomechanics of an osteoporotic spine, may increase the risk of vertebral fractures in adjacent vertebrae. The Task Force was unable to find clear evidence for either an increase or a decrease in fractures after these procedures. The low number of reported events after vertebroplasty over up to 24 months of follow-up, the few reported events in a very small number of clinical trials after kyphoplasty, and no difference detected in two meta-analyses leave the issue of fractures in adjacent vertebrae after these procedures an ongoing clinical concern.

Although disheartening to patients and physicians, the Task Force report also provides some guidance for next steps, including future clinical trials. Given the current body of evidence, the Task Force recommends against additional trials of vertebroplasty unless these are large and adequately powered to alter the conclusion based on current evidence that this procedure is no more effective than placebo. Importantly, the Task Force recommends that this procedure be discontinued in clinical practice. Future efficacy and safety trials of kyphoplasty are needed, but these should include a placebo control group. More research is needed in non-pharmacologic interventions including bracing and exercise.

Embedded in these negative conclusions, however, is perhaps the most important message for patients and physicians: Prevention is clearly superior to vertebral augmentation. Thus, the Task Force recommends that “it is critical that anti-osteoporotic medications are started, continued, or changed (in the case of treatment failure) in patients with recent vertebral fracture." These medications have been shown in clinical trials to reduce the risk of subsequent vertebral fractures by 40% to 70%. This recommendation is clearly aligned with the ASBMR’s secondary fracture prevention initiative (www.secondaryfractures.org), which aims to ensure appropriate treatment of all patients who have suffered a hip or clinical vertebral fracture. More can certainly be done in terms of prevention, but even accomplishing this minimal goal at a time when many (or most) patients who clearly warrant pharmacologic therapy are not receiving it would be a significant public health victory. For those unfortunate patients who have suffered a vertebral fracture, the message of the Task Force is clear: Vertebroplasty does not work to relieve pain from the fracture, and kyphoplasty should generally only be done in the context of a placebo-controlled clinical trial.

Disclosures

BLC has served on a scientific advisory board and received research grants from Shire, Inc., and served on Data Monitoring
Committees for Amgen and Bristol-Myers-Squibb. SK currently serves on scientific advisory boards for Bone Therapeutics, Active Life Scientific, and Surrozen.

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References


